

MOLECULAR TESTING

NAVIGATE BIOPHARMA OFFERS A BROAD RANGE OF MOLECULAR TESTING TO IDENTIFY BIOMARKERS, MUTATIONS, COPY NUMBER VARIATIONS AND FUSIONS (DNA AND RNA) ON MULTIPLE PLATFORMS.

TECHNICAL CAPABILITIES

- Hematologic malignancies and solid tumor
- Digital PCR and qPCR/RT-qPCR
- DNA, RNA and protein expression profiling, copy number analyses. SNV, Indel and fusion detection on hematologic malignancies and solid tumors by multiple technologies and platforms
- Custom molecular tests validated for multiple specimen types: blood, bone marrow, plasma, saliva, fresh tissue, and FFPE after macrodissection
- Fluorescence In Situ Hybridization (FISH)

NEXT GENERATION SEQUENCING ASSAYS

<p>HEMATOLOGIC MALIGNANCIES SERVICES:</p> <ul style="list-style-type: none"> • Myeloid NGS Assay (54 genes) • Comprehensive NGS Panel (236 genes) <ul style="list-style-type: none"> • Can offer subset of panels* 	<p>SOLID TUMOR SERVICES:</p> <ul style="list-style-type: none"> • ALK NGS Assay • Focus NGS Assay (52 genes) • Comprehensive Assay (161 genes) • Comprehensive NGS Panel (236 genes) <ul style="list-style-type: none"> • Can offer subset of panels*
<p>LIQUID BIOPSY SERVICES:</p> <ul style="list-style-type: none"> • Lung cfDNA Assay (11 genes) • Breast cfDNA Assay (10 genes) • Colon cfDNA Assay (14 genes) 	<p>RNA SEQ SERVICES:</p> <ul style="list-style-type: none"> • RNA Pan-Cancer Panel (1385 genes) • Transcriptome Human Gene Expression Kit (>20,000 genes) • Immune Response Research Assay

* Assays offered through partner laboratory

FISH ASSAYS

- ALK Rearrangement (Abbott IVD)
- MET Amplification (LDT)
- ALK Rearrangement (LDT)
- ROS1 Rearrangement
- RET Rearrangement
- Acute Lymphoblastic Leukemia (ALL) Disease Profile
- Chronic Lymphocytic Leukemia (CLL) Disease Profile
- Multiple Myeloma (MM) Disease Profile
- MPN with Eosinophilia Disease Profile

PCR-BASED ASSAYS

- THxID BRAF Mutation Analysis (FDA)
- MLL-PTD Mutation Analysis
- BRAF V600E Mutation Analysis
- UGT1A1 (TA)_n Genotyping by Fragment Analysis
- PIK3CA cobas PCR
- FGFR4/KLB/FGF19 Gene Expression
- Telomere Attrition by qPCR
- BCR-ABL1 Mutation
- Microsatellite Instability (MSI) Analysis
- KRAS Mutation Analysis (FDA)
- EGFR Mutation Analysis

NANOSTRING ASSAYS

- nCounter PanCancer Immune Profiling Panel (IPP)
- nCounter Vantage 3D RNA:Protein Immune Cell Profiling Panel
- nCounter PanCancer Progression Panel (PP)
- nCounter PanCancer RNA Immune Profiling Assay
- nCounter Vantage 3D RNA:Protein Immune Cell Signaling Panel

SERVICES



CUSTOM ASSAY DEVELOPMENT

Navigate BioPharma offers diverse and custom development for clinical biomarkers and diagnostic solutions for use in investigational clinical trials. Our highly skilled, responsive and dedicated team of scientists, project managers and pathologists partner with our pharma and biotech sponsors to create innovative and differentiated solutions.

CLINICAL TRIAL TESTING

Navigate BioPharma provides a broad portfolio of advanced laboratory capabilities utilizing state of the art, diverse technologies that can address clinical biomarker and precision medicine testing needs for every phase of clinical trials (first in human to global pivotal trials). Our integrated solutions address various sponsor needs such as biomarker identification, pharmacodynamics, efficacy readouts, patient inclusion, diagnosis and prognosis. Our comprehensive services team support end-to-end clinical trial testing from sample logistics to project and data management for global clinical trials.

COMPANION DIAGNOSTICS (CoDx)

Navigate BioPharma has broad experience in the development and support of companion diagnostics and CE marking submissions. Our team can support your regulatory needs through its experience in performing risk assessments, IDE, PMA, IRBs as well as CE marking submissions. Our quality systems are designed to ensure compliance with applicable regulatory requirements for drug and diagnostic approvals.

